

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Stinson v. Davol, Inc., et al.
Case No. 2:18-cv-1022

EVIDENTIARY MOTIONS OPINION & ORDER No. 35

Before the Court is Defendants’ Motion to Exclude Opinions of Plaintiff’s Expert Dr. Dipak Panigrahy. (ECF No. 314.) For the reasons that follow, Defendants’ Motion is **GRANTED**.

I. Background¹

Plaintiff’s case is the third bellwether trial selected from thousands of cases in this multidistrict litigation (“MDL”) against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as “shar[ing] common factual questions arising out of allegations that defects in defendants’ polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections.” (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair

¹ For a more complete factual background, the reader is directed to the Court’s summary judgment opinion and order in this case. (Dispositive Motions Order (“DMO”) No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found “a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle.” (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as “slow going and extremely difficult” because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants’ products, Bard Marlex Mesh. (*Id.*) After the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

The crux of Plaintiff’s claims is that Defendants knew of certain risks presented by the PerFix Plug device but marketed and sold the device despite these risks and without appropriate warnings, causing Plaintiff’s injuries. Plaintiff alleges that the polypropylene in the PerFix Plug degrades after implantation, which enhances the chronic inflammatory response in the body. (ECF No. 124 at PageID #4826.) Plaintiff also claims that the inflammation and resulting fibrosis are exacerbated by the PerFix Plug’s shape, weight, and pore size. Plaintiff also claims that the PerFix Plug is susceptible to migration and has a high incidence of chronic pain. (*Id.*) According to Plaintiff, Defendants downplayed the rate and severity of complications caused by the PerFix Plug, even when faced with reports of negative outcomes, which created an unreasonable risk of significant and permanent harm to patients. (*Id.*)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of the PerFix Plug, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings.

II. Legal Standard

Evidentiary rulings are made subject to the district court’s sound discretion, *Frye v. CSX*

Trans., Inc., 933 F.3d 591, 598 (6th Cir. 2019), including the admissibility of expert testimony, *United States v. Dunnican*, 961 F.3d 859, 875 (6th Cir. 2020). This role, however, is not intended to supplant the adversary system or the role of the jury. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531–32 (6th Cir. 2008). Arguments regarding the weight to be given to any testimony or opinions of an expert witness are properly left to the jury. *Id.* “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993).

The burden is on the party offering the expert opinions and testimony to demonstrate “by a preponderance of proof” that the expert evidence is admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert’s testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) (“The Court [in *Daubert*] explained that Rule 702 displays a ‘liberal thrust’ with the ‘general approach of relaxing the traditional barriers to “opinion” testimony.’” (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid. 702 advisory committee’s note to 2000 amendment (“A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.”).

The district court’s role in assessing expert testimony is a “gatekeeping” one, ensuring that only admissible expert testimony is submitted to the jury; its role is not to weigh the expert testimony or determine its truth. *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021) (quoting *Daubert*, 509 U.S. at 597). Expert testimony, *i.e.*, testimony given by “[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education,” is admissible if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, “[t]he Rule 702 analysis proceeds in three stages.” *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). “First, the witness must be qualified by ‘knowledge, skill, experience, training, or education.’ Second, the testimony must be relevant, meaning that it ‘will assist the trier of fact to understand the evidence or to determine a fact in issue.’ Third, the testimony must be reliable.” *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (quoting Fed. R. Evid. 702.).

First, an expert witness must be qualified by “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. “[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.” *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). “[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert’s knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert’s testimony must be for the trier of fact.” *Mannino v. Int’l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party’s expert need only meet the “‘minimal qualifications’ requirement—not one who could teach a graduate seminar on the subject.” *Burgett v. Troy-Bilt LLC*, 579 F. App’x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App’x 440, 446 (6th Cir. 2012) (“An expert’s lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.”).

Second, expert testimony must be relevant. Expert testimony is relevant if it will “help the

trier of fact to understand the evidence or to determine a fact in issue.” *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); Fed. R. Evid. 702(a). “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Daubert*, 509 U.S. at 591 (quoting 3 J. Weinstein & M. Berger, *Weinstein’s Evidence* ¶ 702[02], p. 702–18 (1988)). “This requirement has been interpreted to mean that scientific testimony must ‘fit’ the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify.” *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *Madej*, 951 F.3d at 370 (“Whether an opinion ‘relates to an issue in the case’ or helps a jury answer a ‘specific question’ depends on the claims before the court.”).

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether “the testimony is based on sufficient facts or data,” whether “the testimony is the product of reliable principles and methods,” and whether “the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider “‘testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique’s operation, and general acceptance in the relevant scientific community,’” though these “factors ‘are not dispositive in every case’ and should be applied only ‘where they are reasonable measures of the reliability of expert testimony.’” *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (citations omitted); see *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as “flexible” (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to “make certain that an expert, whether basing testimony upon professional studies

or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire*, 526 U.S. at 152.

III. Analysis

Defendants challenge the opinions and testimony of Plaintiff’s expert Dr. Dipak Panigrahy. (ECF No. 314.) Following Plaintiff’s May 2023 surgery, the Court permitted the parties to supplement their experts’ reports based on the new information from that surgery. (*See* Case No. 18-md-2846, ECF No. 763 (“[T]he parties’ medical experts will be supplementing their reports following Mr. Stinson’s May 2023 surgery[.]”); ECF No. 274.) On August 28, 2023, less than two months before trial, Plaintiff served a report from a new expert, Dr. Panigrahy. (ECF No. 314 at PageID #11219.)

Defendants argue that introduction of a new expert who offers new causation opinions not previously offered in this case goes beyond the limited scope of the allowed supplemental discovery. (*Id.*) Dr. Panigrahy’s opinions are based on “purported impacts on chemical markers from polypropylene mesh, that they contribute to clinical outcomes, or that they last after explant.” (*Id.* at PageID #11223.) According to Defendants, “in more than fifteen years of extensive litigation over polypropylene surgical meshes for hernia repair and other indications, no expert has ever been permitted to offer an opinion on these subjects. To say these are novel opinions and would create a massive expansion of the issues for trial at this late stage is an understatement.” (*Id.*) Defendants point out that Plaintiff could have served a supplemental report from one of his previously disclosed experts rather than attempting to “add a new expert with opinions broader than the original experts.” (*Id.* at PageID #11223–24.) According to Defendants, Dr. Panigrahy’s opinions and testimony go beyond the confines of Rule 26 and are therefore inadmissible.

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony and

requires parties to disclose the identity of any witness that they may use at trial to present evidence under Federal Rules of Evidence 702, 703, or 705. The disclosure “must be accompanied by a written report—prepared and signed by the witness—if the witness is one retained or specially employed to provide expert testimony in the case.” Fed. R. Civ. P. 26(a)(2)(B). The parties must make their expert disclosures “at the time and in the sequence that the court orders,” and “supplement these disclosures when required under Rule 26(e).” Fed. R. Civ. P. 26(a)(2)(D)–(E).

Rule 26(e) requires a party to supplement or correct its disclosure “in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.” Fed. R. Civ. P. 26(e)(1)(A). If a party fails to provide information as required by Rule 26(a) or (e), they may not use that information at trial “unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1). The Sixth Circuit has held that district courts have broad discretion over whether to exclude untimely disclosed expert testimony. *See Pride v. BIC Corp.*, 218 F.3d 566, 578–79 (6th Cir. 2000); *see also Estes v. King’s Daughters Medical Ctr.*, 59 Fed. Appx. 749, 752 (6th Cir. 2003) (“Rule 16 grants district courts broad discretion to enforce their scheduling orders.”).

The Court anticipated supplemental discovery given Plaintiff’s May 2023 surgery and changes to his medical condition, but discovery was not completely reopened. Rather, the Court allowed limited discovery based only on the new information. Instead of supplementing his existing expert reports, Plaintiff added an expert who has never been used in this MDL. Additionally, the new expert bases his opinion on a theory regarding chemical markers that has not been introduced in this MDL or, according to Defendants, in “more than fifteen years of extensive litigation over polypropylene surgical meshes for hernia repair and other indications.”

(ECF No. 314 at PageID #11223.) Plaintiff does not explain why he offered a new expert instead of offering a supplemental report from one of his existing experts, and fails to address the fact that Dr. Panigrahy's opinions are based on a theory completely new to this MDL and to this case specifically. The scope of supplemental discovery was limited and was not intended to allow the parties to present new and complicated theories on the eve of trial. Accordingly, Dr. Panigrahy's opinions were not properly provided under Rule 26 of the Federal Rules of Civil Procedure.

Plaintiff argues that Rule 26 permits supplementation "to the extent the opposing party is not prejudiced." (ECF No. 323 at PageID #11902.) Plaintiff claims that Defendants have had "ample opportunity" to address the report. (*Id.*) Defendants correctly point out that it is not their burden to show that they were prejudiced, but it is Plaintiff who is required to show substantial justification or harmlessness. (ECF No. 339 at PageID #12738.)

If the supplemental report was not proper under Rule 26, it still may be used at trial if the omission was substantially justified or harmless. Fed. R. Civ. P. 37(c)(1). To address whether a party's omitted or late disclosure is substantially justified or harmless, the Court must consider:

- (1) the surprise to the party against whom the evidence would be offered;
- (2) the ability of that party to cure the surprise;
- (3) the extent to which allowing the evidence would disrupt the trial;
- (4) the importance of the evidence; and
- (5) the nondisclosing party's explanation for its failure to disclose the evidence.

Howe v. City of Akron, 801 F.3d 718, 748 (6th Cir. 2015) (internal citations omitted). Plaintiff does not address the *Howe* factors in his response to Defendants' motion. The Court will address each factor in turn.

The Court first considers surprise to the party against whom the evidence would be offered. As Defendants point out, Dr. Panigrahy offers opinions that have not been offered in this litigation, nor in any other polypropylene mesh litigation. Given Plaintiff served a supplemental report from

a brand new expert whose opinions are based on theories completely new to this case, this factor favors Defendants.

Next, the Court considers the ability of Defendants to cure that surprise. While Plaintiff claims that Defendants had “ample opportunity” to address Dr. Panigrahy’s report, as Defendants point out, this new expert’s report containing a novel theory in this case was served shortly before trial. This factor also weighs in favor of Defendants.

Next, the Court considers the extent to which allowing the evidence would disrupt the trial. Dr. Panigrahy offers opinions based on a novel theory and examined “over 4,700 publications” in forming his opinions. Allowing such an expansion would greatly disrupt trial, and this factor also weighs in Defendants’ favor.

Next, the Court considers the importance of the evidence. Plaintiff does not address the *Howe* factors in response to Defendants’ motion, and therefore does not present an argument about how important Dr. Panigrahy’s opinions are to his case. Instead, he argues that Dr. Panigrahy’s report is “well-within the scope” of the permitted supplemental discovery and was not specifically forbidden. Because Plaintiff does not address the importance of this evidence, the Court will consider this factor neutral.

Finally, the Court must consider the non-disclosing party’s explanation for his failure to disclose the evidence. Plaintiff offers no acknowledgment of or explanation for why he did not supplement an existing expert’s report and instead sought to introduce a new expert on the eve of trial. Plaintiff also does not address Defendants’ arguments that Dr. Panigrahy’s opinions are based on a theory new to this case and to polypropylene mesh litigation in general. Plaintiff merely contends that “Dr. Panigrahy’s vast knowledge of inflammatory chemical markers simply illustrates that he is a top-tier expert in the field of inflammation.” (ECF No. 323 at PageID

#11904–05.) Therefore, this factor also favors Defendants.

Plaintiff has not shown that his late disclosure of a new expert with a new theory is substantially justified nor harmless. Accordingly, Defendants’ motion to exclude Dr. Panigrahy’s opinions and testimony is granted.

IV. Conclusion

For the reasons set forth above, Defendants’ Motion to Exclude Opinions of Plaintiff’s Expert Dr. Dipak Panigrahy (ECF No. 314) is **GRANTED**.

IT IS SO ORDERED.

10/25/2023
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE